

Andrew J. Miller  
 Stuart D. Sender  
 Alan H. Pollack  
 Ellen T. Lowenthal  
 Michael W. Choi  
 BUDD LARNER, P.C.  
 150 John F. Kennedy Parkway  
 Short Hills, New Jersey 07078  
 Tel: (973) 379-4800

*Attorneys for Defendants  
 Dr. Reddy's Laboratories, Ltd. and  
 Dr. Reddy's Laboratories, Inc.*

UNITED STATES DISTRICT COURT  
 FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, and POZEN INC.,	:	Civil Action No. 11-2317 (JAP-DEA)
	:	
Plaintiffs,	:	
	:	
v,	:	
DR. REDDY'S LABORATORIES INC. and:	:	
DR. REDDY'S LABORATORIES LTD.,	:	
Defendants.	:	

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN INC.,	:	Civil Action No. 11-04275 (JAP-DEA)
	:	
Plaintiffs,	:	
	:	
v.	:	
LUPIN LTD. and LUPIN	:	
PHARMACEUTICALS INC.,	:	
Defendants.	:	

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN INC.,	:	Civil Action No. 11-06348 (JAP-DEA)
	:	
Plaintiffs,	:	
	:	
v.	:	
ANCHEN PHARMACEUTICALS, INC.,	:	
Defendants.	:	

ASTRAZENECA AB, ASTRAZENECA LP, and POZEN INC.,	:	Civil Action No. 13-00091 (JAP)(DEA)
	:	
Plaintiffs,	:	
	:	
v,	:	
DR. REDDY'S LABORATORIES INC. and:	:	(Filed electronically)
DR. REDDY'S LABORATORIES LTD.,	:	
Defendants.	:	MOTION DATE: August 19, 2013

**DRL'S MEMORANDUM OF LAW IN OPPOSITION  
 TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY  
 JUDGMENT THAT U.S. PATENT NO. 6,926,907 IS NOT INVALID**

## TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES .....	ii
I. INTRODUCTION .....	1
II. STATEMENT OF FACTS .....	3
III. ARGUMENT .....	6
A. THE COURT LACKS SUBJECT MATTER JURISDICTION TO HEAR POZEN’S SUMMARY JUDGMENT MOTION .....	6
1. There is No Case or Controversy With Respect to Validity in Action No. 13-00091 Because DRL Dropped Its Invalidity Defense in that Action .....	6
2. Subject Matter Jurisdiction Must Exist at All Stages of the Case, and Invalidity is No Longer at Issue in Action No. 13- 00091.....	8
B. POZEN HAS NO “NEED” FOR SUMMARY JUDGMENT OF VALIDITY BECAUSE THE PATENT IS PRESUMED VALID.....	9
C. THERE CAN BE NO COLLATERAL ESTOPPEL IN ANY EVENT.....	11
1. Collateral Estoppel Cannot Apply Because There Must Be “A Final Judgment on the Merits”.....	12
2. Collateral Estoppel Cannot Apply Because Validity Will Not Have Been “Actually Litigated” .....	13
D. SUMMARY JUDGMENT IS NOT AN APPROPRIATE RELIEF .....	15
IV. CONCLUSION.....	16

## TABLE OF AUTHORITIES

	<u>Page</u>
 <u>Cases</u>	
<i>ACCO Brands, Inc. v. PC Guardian Anti-Theft Prods., Inc.</i> , 592 F. Supp. 2d 1208 (N.D. Cal. 2008).....	10, 11
<i>Adolph Coors Co. v. IRS</i> , 519 F.2d 1280 (10th Cir. 1975).....	14
<i>Aircraft Tech. Publishers v. Avantext, Inc.</i> , No. 07-4154, 2009 U.S. Dist. LEXIS 106526 (N.D. Cal. Nov. 16, 2009).....	15
<i>Amadeo v. Principal Mut. Life Ins. Co.</i> , 290 F.3d 1152 (9th Cir. 2002) .....	14
<i>Chicago Truckers Drivers Pension Fund v. Century Motor Freight, Inc.</i> , 125 F.3d 526 (7th Cir. 1997).....	14
<i>Hoffman-La Roche Inc. v. Mylan Pharms. Inc.</i> , No. 09-1692, 2009 U.S. Dist. LEXIS 114784 (D.N.J. Dec. 9, 2009) .....	8
<i>Howes v. Zircon Corp.</i> , 992 F. Supp. 957 (N.D. Ill. 1998).....	8
<i>Janssen Pharmaceutica, N.V. v. Apotex, Inc.</i> , No. 06-1020, 2007 U.S. Dist. LEXIS 75967 (D.N.J. Oct. 11, 2007), <i>aff'd</i> , 540 F.3d 1353 (Fed. Cir. 2008) .....	6-7
<i>Jenkins v. Fields</i> , No. 95-9603, 1996 U.S. Dist. LEXIS 5852 (S.D.N.Y. Apr. 30, 1996).....	6
<i>King Pharms., Inc. v. Sandoz, Inc.</i> , No. 08-5974, 2010 U.S. Dist. LEXIS 50163 (D.N.J. May 19, 2010).....	7
<i>Malibu Media v. Does</i> , No. 12-2078, 2013 U.S. Dist. LEXIS 55985 (E.D. Pa. Mar. 6, 2013) .....	7, 15-16
<i>Meds. Co. v. Teva Parenteral Meds., Inc.</i> , No. 09-750, 2011 U.S. Dist. LEXIS 54785 (D. Del. May 23, 2011) .....	8
<i>New Eng. Braiding Co. v. A.W. Chesterton Co.</i> , 970 F.2d 878 (Fed. Cir. 1992) .....	12
<i>Orthokinetics, Inc. v. Safety Travel Chair, Inc.</i> , 806 F.2d 1565 (Fed. Cir. 1986) .....	9, 10
<i>In re Papst Licensing GmbH &amp; Co. KG Litig.</i> , 273 F.R.D. 339 (D.D.C. 2011).....	7
<i>Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.</i> , 763 F. Supp. 2d 671 (D. Del. 2010) .....	14
<i>Robotic Vision Sys., Inc. v. View Eng'g., Inc.</i> , 189 F.3d 1370 (Fed. Cir. 1999).....	10, 11
<i>Seborowski v. Pittsburgh Press Co.</i> , 188 F.3d 163 (3d Cir. 1999).....	12
<i>Serby v. First Alert, Inc.</i> , No. 09-4229, 2013 U.S. Dist. LEXIS 45942 (E.D.N.Y. Mar. 27, 2013) .....	15
<i>Smith v. Hayman</i> , No. 09-2602, 2012 U.S. Dist. LEXIS 44888 (D.N.J. May 30, 2012), <i>aff'd on other grounds</i> , 489 F. App'x 544 (3d Cir.), <i>cert. denied</i> , 133 S. Ct. 762 (2012).....	12

<i>Stratoflex, Inc. v. Aeroquip Corp.</i> , 713 F.2d 1530 (Fed. Cir. 1983) .....	12
<i>Sunrise Med. HHG, Inc. v. Airsep Corp.</i> , 95 F. Supp. 2d 348 (W.D. Pa. 2000) .....	12
<i>Teradyne, Inc. v. Hewlett-Packard Co.</i> , No. 91-0344, 1994 U.S. Dist. LEXIS 8630 (N.D. Cal. June 21, 1994) .....	8
<i>Teva Pharm. Indus., Ltd. v. Dr. Reddy's Lab., Ltd.</i> , No. 07-2894, 2008 U.S. Dist. LEXIS 16958 (D.N.J. Mar. 4, 2008) .....	8
<i>United States v. Young</i> , 804 F.2d 116 (8th Cir. 1986) .....	15
<i>Wonderland Nurserygoods Co. v. Thorley Indus., LLC</i> , No. 12-196, 2013 U.S. Dist. LEXIS 80003 (W.D. Pa. June 7, 2013) .....	7

### **Statutes and Regulations**

21 C.F.R. § 314.94(a)(12)(i)(A)(4) .....	4
21 U.S.C. § 355(j)(2)(A)(vii)(IV) .....	4
35 U.S.C. § 282(a) .....	9

### **Rules**

L. Pat. R. 3.6(c) .....	7
-------------------------	---

### **Other Authorities**

<i>Restatement (Second) of Judgments</i> § 27 (1980) .....	12, 13, 15
--	------------

## **I. INTRODUCTION**

Pozen's three-page summary judgment motion asks the Court to render a decision on an issue as to which there is no dispute. This non-dispute arises from DRL's decision to forgo serving invalidity contentions with respect to U.S. Patent No. 6,926,907 ("the '907 patent") in the later of two DRL cases involving generic DRL Vimovo products currently pending before this Court, *i.e.* Action No. 13-00091 ("DRL II"), and only to pursue its non-infringement defense in that case. In other words, DRL decided – as is its right – to narrow the issues and not proceed with a defense of invalidity with respect to the '907 patent in DRL II. Thus, DRL served only non-infringement contentions, evidencing its intention to defend the DRL II lawsuit solely on the basis of non-infringement.

Having designed around the claims of the '907 patent in developing its second generic Vimovo ANDA product (which is the only product at issue in DRL II), DRL elected to rely solely on its strong non-infringement defense. Non-infringement is, of course, a complete defense to an allegation of patent infringement, an issue on which Pozen as the patentee bears the burden of proof. DRL does not need, in DRL II, to litigate invalidity, an issue on which it would bear the burden of proof by clear and convincing evidence, and has chosen not to do so. DRL is litigating invalidity in its first Vimovo ANDA case (11-2317, "DRL I"), but that case concerns a different generic Vimovo ANDA product, whose formulation does not provide DRL with a non-infringement defense. Thus, in DRL I, DRL asserts only invalidity defenses, whereas in DRL II, DRL asserts only non-infringement.

Nevertheless, and in response to nothing, Pozen served 63 pages of so-called "validity contentions" in DRL II. Pozen's pursuit of this non-dispute unnecessarily multiplies the

proceedings, and it has already spawned a host of letters to both Judge Pisano and Judge Arpert and court conferences with both.<sup>1</sup>

Pozen's service of its extensive "validity contentions" is not benign. The "validity contentions" Pozen seeks to interpose in DRL II are substantially the same as the "compromise validity contentions" Judge Arpert refused to permit Pozen to propound in DRL I just a few months ago. (*See* D.E. 134.) Ever since it lost on the DRL I contention issue in March, Pozen has been engaging in self-help, trying to get those 63 pages of contentions into some Vimovo case against DRL. Still refusing to accept Judge Arpert's denial of its motion to amend its validity contentions in DRL I as final, Pozen asserts in its June 28, 2013 letter, "The filing of a second case following from DRL's decision to file a second ANDA is a changed circumstance that provides good cause for amending the Responses in DRL I." (D.E. 151, at 3.) How DRL's filing of a second ANDA on a different product, resulting in a second ANDA case in which DRL has not propounded any invalidity contentions amounts to "a changed circumstance that provides good cause for amending the [Validity] Responses in DRL I" is a head-scratcher. As Judge Arpert pointed out at the July 24 status conference, the appropriate tack would be for Pozen to move to amend its contentions in DRL I based on the alleged changed circumstances.

With this summary judgment motion, Pozen now seeks to use the non-dispute over validity of the '907 patent in DRL II to dispose of the validity dispute in DRL I by sleight of hand. (*See* D.E. 151.) Pozen asks the Court first to grant it summary judgment on an issue on which there is no case or controversy in DRL II, and then to give such an opinion preclusive

---

<sup>1</sup> DRL intends to move separately to strike Pozen's validity contentions in DRL II as Judge Arpert instructed during the parties' July 24 status conference.

effect in DRL I, in which the validity of the ‘907 patent is actually being contested. The Court should dismiss Pozen’s motion for lack of subject matter jurisdiction.

Pozen’s stated goal of using its summary judgment motion to preclude DRL from challenging the validity of the ‘907 patent in DRL I is futile. Collateral estoppel could not apply because there would be neither a judgment on the merits nor would the issue of the validity or invalidity of the ‘907 patent have been actually litigated in DRL II.

## **II. STATEMENT OF FACTS**

As Pozen stated in its June 28, 2013 letter to Judge Arpert (D.E. 151), “DRL has filed two separate ANDAs” relating to patents for Vimovo. “Those filings came nearly two years apart and have resulted in two separate Hatch-Waxman cases,” No. 11-2317, filed on April 21, 2011 (“DRL I”) and No. 13-00091, filed on January 4, 2013 (“DRL II”). (D.E. 151, at 1.)

What Pozen does not say is that DRL’s two separate ANDAs, and the two separate Hatch-Waxman cases, pertain to two different ANDA products. DRL developed a different formulation for its second generic Vimovo ANDA product specifically to avoid, and therefore not infringe, the claims of the ‘907 patent. Thus, in DRL I, DRL asserts invalidity, but not non-infringement. In DRL II – the case to which Pozen’s summary judgment motion is ostensibly addressed – DRL asserts non-infringement, but not invalidity. This second case is proceeding as a pure non-infringement case due to DRL’s design-around.

Pozen’s June 28 letter to Judge Arpert inaccurately states that “DRL certified to the FDA that the claims of the ‘907 Patent were, *inter alia*, invalid in connection with its second ANDA. . . .” (D.E. 151, at 1.) DRL actually certified to FDA in the Paragraph IV Certification of its ANDA No. 204206 that the ‘907 patent was “invalid, unenforceable or will not be infringed by the manufacture, use or sale of Dr. Reddy’s Naproxen & Esomeprazole Magnesium

delayed release tablets for which this [ANDA] is submitted.” The six-line “Paragraph IV Certification” included in ANDA No. 204206 (the ANDA at issue in DRL II) simply invoked and echoed the applicable language of the Hatch-Waxman Act and its implementing regulation. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (requiring certification “that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] application is submitted” (emphasis added)); 21 C.F.R. § 314.94(a)(12)(i)(A)(4) (requiring certification “that the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the abbreviated application is submitted. The applicant shall entitle such a certification ‘Paragraph IV Certification.’” (emphasis added)). The totality of DRL’s Paragraph IV Certification to FDA with respect to the ‘907 patent is reproduced below:

**Paragraph IV Patent Certification re: U.S. Patent No. 6,926,907.**

In accordance with Section 505(j)(2)(A)(vii)(IV) and 21 CFR §314.94(a)(12)(i)(A)(4), Dr. Reddy’s Laboratories Limited (“Dr. Reddy’s”) certifies that the following patents listed for VIMOVO® delayed release tablets, equivalent to equivalent to 500 mg /20 mg base and 375 mg /20 mg base are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Dr. Reddy’s Naproxen & Esomeprazole Magnesium delayed release tablets for which this abbreviated new drug application (“ANDA”) is submitted.

- US Patent No. 6,926,907– Expiry Date: Feb. 28, 2023

It is true that DRL’s memorandum accompanying its statutory Notice Letter to Plaintiffs for its second generic Vimovo ANDA raised the issue of invalidity – a not uncommon occurrence in the Hatch-Waxman realm. It is also true that DRL’s Answer in DRL II included invalidity as a Second Affirmative Defense, stating, “At least claims 1, 5, 9-17, 21-24, 28-29, 32-35, 37, 41-42, 45-48, and 50-55 of the ‘907 patent are invalid under Title 35 United States Code,



including, *inter alia*, §§ 101, 102, 102, 112 and for double patenting.” (D.E. 5 in Action No. 13-00091, Answer ¶ 84.)

However, when the time came to propound invalidity contentions pursuant to the Local Patent Rules and the scheduling order in DRL II, (D.E. 145), DRL chose not to propound any. Instead, DRL narrowed the issues and provided only non-infringement contentions. DRL made the “decision to forgo any invalidity contentions” in this case, (*see* DRL’s June 26, 2013 to Judge Arpert, (D.E. 147), at 1), because, unlike in DRL I, there was no need to litigate the issue of invalidity in DRL II because non-infringement provides a complete defense. DRL surely has the right under the Local Patent Rules (as well as the Federal Rules of Civil Procedure) to choose not to pursue all of the legal theories set forth in its pleadings and in its pre-litigation communications with its adversaries. Thus, Pozen has no “need” to respond to DRL’s Answer and Notice Letter – they are superseded by DRL’s non-infringement contentions. (*See id.* at 2.)

Nonetheless, despite the absence of any invalidity contentions in DRL II, Pozen served “validity contentions” that are substantially the same as the “compromise validity contentions” that Judge Arpert refused to permit Pozen to submit in DRL I earlier this year. (*See* D.E. 134.) Indeed, when asked why it had submitted validity contentions even though DRL had not served any invalidity contentions in DRL II, Pozen candidly admitted that its validity contentions responded to DRL’s invalidity contentions in DRL I, DRL’s Paragraph IV Certification submitted to FDA, and DRL’s three-line affirmative defense of invalidity in DRL II. (*See* D.E. 151, at 1.)

The parties discussed the contentions issue with Judge Arpert during a June 21, 2013 status conference, and he directed that they submit letters explaining this issue further. Those letters followed, (*see* D.E. 147, D.E. 151), along with Pozen’s summary judgment motion, filed

as D.E. 152 and also attached to its June 28 letter to Judge Arpert (D.E. 151). Notably, DRL has offered to withdraw its affirmative defense of invalidity in this case, Action No. 13-00091, but Pozen declined that offer.

Pozen's June 28 letter to Judge Arpert reveals the true motivation for its summary judgment motion: "Summary judgment on the issue of validity in this case will preclude DRL from litigating the same issue in DRL I." (D.E. 151, at 2.) Pozen acknowledges that DRL has "decided not to put forward evidence of invalidity in this case" and that DRL "does not contest the validity of the patent." (*Id.*) Notwithstanding the lack of a dispute as to the validity of the '907 patent in DRL II, Pozen incorrectly asserts that summary judgment in its favor "may moot the entire issue in both cases." (*Id.* (emphasis added).)

### **III. ARGUMENT**

#### **A. THE COURT LACKS SUBJECT MATTER JURISDICTION TO HEAR POZEN'S SUMMARY JUDGMENT MOTION**

##### **1. There is No Case or Controversy With Respect to Validity in Action No. 13-00091 Because DRL Dropped Its Invalidity Defense in that Action**

Pozen's summary judgment motion should be dismissed because the Court lacks subject matter jurisdiction to consider it. DRL has made clear to Pozen and the Court that it no longer asserts invalidity as an affirmative defense in DRL II. Accordingly, there is no case or controversy with respect to the validity of the '907 patent in DRL II. *See Jenkins v. Fields*, No. 95-9603, 1996 U.S. Dist. LEXIS 5852, at \*20 n.3 (S.D.N.Y. Apr. 30, 1996) ("there is no case or controversy in this case as to that issue because defendants are not asserting such a defense...."); *see also Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, No. 06-1020, 2007 U.S. Dist. LEXIS 75967, at \*6 (D.N.J. Oct. 11, 2007) (granting motion to dismiss counterclaims for declaratory judgment of non-infringement for lack of subject matter jurisdiction due to patentee's grant of

covenant not to sue “because there is no case or controversy surrounding the patents Defendant alleges are in issue”), *aff’d*, 540 F.3d 1353 (Fed. Cir. 2008).

“As *Rule 8(c)(1)* makes clear, affirmative defenses are used to preserve a defendant’s potential arguments. . . .” *Malibu Media v. Does*, No. 12-2078, 2013 U.S. Dist. LEXIS 55985, at \*7-\*8 (E.D. Pa. Mar. 6, 2013) (emphasis added). Thus, DRL appropriately asserted invalidity in its Answer to preserve it as a potential defense. However, if DRL intended to pursue an invalidity defense, it would have had to propound invalidity contentions within the time allotted by this Court’s Scheduling Order and the Local Patent Rules. *See* L. Pat. R. 3.6(c). “The purpose of invalidity contentions is to require a party to . . . provide notice of the accusing party’s specific theories of invalidity.” *Wonderland Nurserygoods Co. v. Thorley Indus., LLC*, No. 12-196, 2013 U.S. Dist. LEXIS 80003, at \*7 (W.D. Pa. June 7, 2013).

“[C]ontentions are an extension of notice pleadings, requiring more specificity in order to reign in and streamline discovery.” *Id.* at \*8. “The purpose of [local patent rules] is to ‘prevent the case stagger[ing] for months without clear direction’ by ‘focusing discovery on building precise final infringement or invalidity contentions and narrowing issues for Markman, summary judgment[,] trial, and beyond.’” *In re Papst Licensing GmbH & Co. KG Litig.*, 273 F.R.D. 339, 343 (D.D.C. 2011) (emphasis added) (citation omitted). As this Court has recognized, “The [Local Patent] rules are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.” *King Pharms., Inc. v. Sandoz, Inc.*, No. 08-5974, 2010 U.S. Dist. LEXIS 50163, at \*10 (D.N.J. May 19, 2010) (Arpert, J.) (internal citation omitted). Therefore, when DRL did not serve any invalidity contentions, invalidity dropped out of the case. Based on DRL’s contentions, the legal theory in DRL II has been narrowed to the issue of infringement.

**2. Subject Matter Jurisdiction Must Exist at All Stages of the Case, and Invalidity is No Longer at Issue in Action No. 13-00091**

Pursuant to this District’s Local Patent Rules, when a party narrows its asserted claims in contentions, the Court loses subject matter jurisdiction over those issues not asserted in the contentions, even if they had been asserted in the complaint. *See Hoffman-La Roche Inc. v. Mylan Pharms. Inc.*, No. 09-1692, 2009 U.S. Dist. LEXIS 114784, at \*10, \*20-21 (D.N.J. Dec. 9, 2009) (accused infringer failed to demonstrate a live case or controversy with respect to claims whose assertion patentee did not carry forward in local patent rule infringement contentions).

That is consistent with the principle that “[c]ourts have found that there is no case in controversy regarding claims that are no longer alleged to be infringed.” *Meds. Co. v. Teva Parenteral Meds., Inc.*, No. 09-750, 2011 U.S. Dist. LEXIS 54785, at \*1 n.1 (D. Del. May 23, 2011) (emphasis added) (“As Plaintiff has represented to this Court that it is not asserting these claims, and thereby waiving its right to assert infringement on these claims, the Court finds that there is no case-in-controversy regarding the unasserted claims.”); *see also Teva Pharm. Indus., Ltd. v. Dr. Reddy’s Lab., Ltd.*, No. 07-2894, 2008 U.S. Dist. LEXIS 16958, at \*9-\*11 (D.N.J. Mar. 4, 2008) (denying accused infringer’s motion for partial summary judgment of invalidity for lack of subject matter jurisdiction because “[t]he case or controversy requirement must be evaluated claim by claim . . . and Teva has conceded that it is not pursuing an infringement claim as to claim 1 of the ‘008 patent”); *Howes v. Zircon Corp.*, 992 F. Supp. 957, 959 (N.D. Ill. 1998) (“I have no jurisdiction to address Zircon’s motion for summary judgment” of non-infringement of claims as to which plaintiffs “no longer allege infringement . . . and thus no present case or controversy exists regarding their infringement”); *Teradyne, Inc. v. Hewlett-Packard Co.*, No. 91-0344, 1994 U.S. Dist. LEXIS 8630, at \*3 & n.3 (N.D. Cal. June 21, 1994) (refusing to

consider motion for partial summary judgment of invalidity because “to the extent HP is no longer asserting Claims 1 and 4, this court has no jurisdiction to determine the validity or invalidity of those claims”).

As discussed above, DRL has dropped the affirmative defense of invalidity by forgoing the service of any invalidity contentions. Since DRL is no longer asserting invalidity in DRL II, there is no case or controversy on the issue of invalidity in this case. Therefore, Pozen’s motion for summary judgment should be dismissed for lack of subject matter jurisdiction.

**B. POZEN HAS NO “NEED” FOR SUMMARY JUDGMENT OF VALIDITY BECAUSE THE PATENT IS PRESUMED VALID**

---

During the June 21, 2013 court conference Pozen argued that it had the “duty and obligation” to defend the validity of the ‘907 patent in response to representations DRL had made to FDA and others. But this is not so.

“A patent shall be presumed valid...The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” 35 U.S.C. § 282(a) (emphasis added). DRL is not asserting invalidity in DRL II. Accordingly, the presumption of validity holds, and there is no need for a judicial determination of validity.<sup>2</sup> Indeed, in *Orthokinetics, Inc. v. Safety Travel Chair, Inc.*, 806 F.2d 1565 (Fed. Cir. 1986), on which Pozen relies, the court stated, “A patent being presumed valid at birth, § 282, a patentee need submit *no* evidence in support of a conclusion of validity in support of a conclusion of validity by a court or a jury.” *Id.*

---

<sup>2</sup> Perhaps recognizing this weakness, Pozen ignores DRL’s decision not to assert invalidity, and instead, attempts to recharacterize it as a “deci[sion] not to put forward evidence of invalidity in this case.” (Pozen June 28 letter (D.E. 151), at 2 (emphasis added).)

at 1570 (emphasis in the original).<sup>3</sup> The court went on to chastise patentees who “have historically sought to ‘go first’ with testimony on validity. . . . The resulting erroneous but clear impression that patentees bear a burden of ‘proving validity’ has frequently resulted in cluttered records, irrelevant detours, undue burdens on the judicial process, and unnecessary work for the trial court.” *Id.* at 1571.

Moreover, although Pozen cites cases purportedly setting forth the “Standard for Summary Judgment of Validity,” (Pozen Br. at 1), the Federal Circuit cases on which it relies for that principle are not summary judgment cases. *Robotic Vision Sys., Inc. v. View Eng’g., Inc.*, 189 F.3d 1370 (Fed. Cir. 1999), affirmed a district court’s determination following a bench trial that the patent-in-suit was not invalid for obviousness. *Id.* at 1371. In *Orthokinetics*, the court reversed the grant of a judgment notwithstanding the verdict holding that the patents-in-suit were invalid, and instructed the district court to reinstate the jury’s verdicts. 806 F.2d at 1567.

In the only other patent case cited in Pozen’s brief, *ACCO Brands, Inc. v. PC Guardian Anti-Theft Prods., Inc.*, 592 F. Supp. 2d 1208 (N.D. Cal. 2008) (*see* Pozen Br. at 2), a motion for summary judgment of validity was made in response to motions for summary judgment of invalidity. *Id.* at 1221-22. Clearly DRL has not moved for summary judgment of invalidity here.

The cases on which Pozen relies are inapposite for the further reason that the defendants in those cases actually asserted invalidity throughout lengthy litigations. *See Orthokinetics*, 806 F.2d at 1569-70 (invalidity defense pursued by defendant through three years of litigation,

---

<sup>3</sup> In the sentence before the one quoted in Pozen’s parenthetical (Pozen Br. at 1), the court did caution patentees, however, that “[i]f the patent challenger introduces evidence that might lead to a conclusion of invalidity, a patentee would be well advised to introduce evidence sufficient to rebut that of the challenger.” *Orthokinetics*, 806 F.2d at 1570.

including trial); *Robotic*, 189 F.3d at 1371, 1373 (two years of litigation culminating in bench trial determining that patent was not invalid for obviousness); *ACCO Brands*, 592 F. Supp. 2d at 1208, 1215 (defendant Fellowes asserted invalidity throughout more than three years of litigation, including “assert[ing] [its invalidity] claim through its interrogatory responses and deposition testimony”).<sup>4</sup> In contrast, DRL has not substantively asserted invalidity in this case and swiftly removed it from the case at an early stage by serving no invalidity contentions. The early narrowing of this case through the dropping of issues is one of the fundamental goals of the Local Patent Rules. Pozen’s effort to expand this case, rather than narrow it, runs counter to this fundamental Local Patent Rule goal.

**C. THERE CAN BE NO COLLATERAL ESTOPPEL IN ANY EVENT**

Pozen’s contention letter to Judge Arpert, (D.E. 151, at 2), explains that it seeks summary judgment of validity in DRL II to preclude DRL from litigating invalidity in DRL I. However, Pozen’s attempt to parlay the possibility of summary judgment of validity in DRL II to preclude DRL from litigating invalidity in DRL I is futile. Any summary judgment of validity in this case would not be entitled to preclusive effect in DRL I for at least two reasons. First, even if the Court were to grant summary judgment to Pozen on the theory that “[w]ithout any evidence to either support its affirmative defense of invalidity or controvert Plaintiffs’ prayer for a judgment of validity, DRL cannot carry its burden” of proving invalidity, (Pozen Br. at 2), any such judgment would not be on the merits. Second, collateral estoppel could not apply because the issue of validity would not have been actually litigated.

---

<sup>4</sup> The *Acco* case can be further distinguished because defendant Fellowes had a co-defendant in the case that submitted invalidity contentions and also filed a motion for summary judgment of patent invalidity. Fellowes would have benefited from any invalidity decision obtained by its co-defendant regardless of its own invalidity contentions.

**1. Collateral Estoppel Cannot Apply Because There Must Be “A Final Judgment on the Merits”**

Pozen’s sole argument for summary judgment is that DRL will be unable to overcome the ‘907 patent’s “presumption of validity” without invalidity contentions. (*See* Pozen Br. at 1-2 (“‘There is a strong presumption of validity for issued patents,’ and the accused infringer asserting invalidity ‘bears the burden of showing invalidity. . . .’” and “[w]ithout any invalidity contentions, DRL will not be able to put forward any facts to establish invalidity of the ‘907 Patent”).) However, for collateral estoppel to apply, “there must be a final judgment on the merits.” *Seborowski v. Pittsburgh Press Co.*, 188 F.3d 163, 169 (3d Cir. 1999); *see also Smith v. Hayman*, No. 09-2602, 2012 U.S. Dist. LEXIS 44888, at \*47 (D.N.J. May 30, 2012), *aff’d on other grounds*, 489 F. App’x 544 (3d Cir.), *cert. denied*, 133 S. Ct. 762 (2012). Pozen’s argument also ignores the fact that DRL served invalidity contentions in DRL I and Pozen served responses in DRL I.

Thus, collateral estoppel would not apply because Pozen’s motion would be decided on a purely procedural device, which by definition cannot be “on the merits.” *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983) (“The presumption [of validity], like all legal presumptions, is a procedural device, not substantive law.”); *New Eng. Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992) (“The presumption [of validity] acts as a procedural device which places . . . the ultimate burden of persuasion of invalidity at trial on the alleged infringer.”); *Sunrise Med. HHG, Inc. v. Airsep Corp.*, 95 F. Supp. 2d 348, 450 (W.D. Pa. 2000) (The presumption of validity “is procedural, not substantive.”). Therefore, Pozen’s motion would be futile for collateral estoppel purposes and for that reason too should be dismissed.



## 2. Collateral Estoppel Cannot Apply Because Validity Will Not Have Been “Actually Litigated”

Any possible finding of validity in DRL II, where DRL is not asserting invalidity, cannot have preclusive effect in DRL I because an issue needs to be “actually litigated” for collateral estoppel to apply. *See Restatement (Second) of Judgments* § 27 (1980) (“When an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim.” (emphasis added)).

The *Restatement* establishes why Pozen’s three-page summary judgment motion cannot yield an “actually litigated” result. Specifically, comment (e) of this *Restatement*, entitled “*Issues not actually litigated*,” explains that:

- “There are many reasons why a party may choose not to raise an issue, or to contest an assertion, in a particular action.” (*Here, for example, DRL has no need to argue invalidity in its second case and, in fact, if it succeeds in its non-infringement argument will benefit from not invalidating the patent.*)
- “[I]f preclusive effect were given to issues not litigated, the result might serve to discourage compromise, to decrease the likelihood that the issues in an action would be narrowed by stipulation and thus intensify litigation.” (*Here, for example, DRL would not choose to narrow the issues in DRL II by dropping a validity challenge if the effect of that required DRL to concede validity in the DRL I.*)
- “An issue is not actually litigated if the defendant might have interposed it as an affirmative defense but failed to do so; nor is it actually litigated if it is raised by a material allegation of a party’s pleading but is admitted (explicitly or by virtue of a failure to deny) in a responsive pleading.” (*Here, the issue would not be litigated because DRL’s failure to raise it in contentions would be an admission of or a failure to deny validity.*)
- “In the case of a judgment entered by confession, consent, or default, none of the issues is actually litigated. Therefore, the rule of this Section does not apply with respect to any issue in a subsequent action.” (*Here, because Pozen’s summary judgment motion would be equivalent to a default judgment, it cannot be “actually litigated.”*)

Courts in the Third Circuit and elsewhere have held that matters were not “actually litigated” in situations like this one. In *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 763 F. Supp. 2d 671 (D. Del. 2010), the accused infringer generally pled patent invalidity in its answer in the first action, but only litigated obviousness. The court held that issue preclusion did not apply to an invalidity defense of anticipation in a second trial regarding the same patent because anticipation was not “actually litigated,” though obviousness was. *Id.* at 680. If the assertion of invalidity in general in an answer (even citing the statute governing anticipation and other invalidity defenses),<sup>5</sup> plus subsequent litigation through trial of obviousness cannot preclude later litigation of anticipation of the same patent, DRL’s dropping its affirmative defense of all invalidity issues cannot preclude any invalidity contentions in a separate case. Moreover, where an issue is not argued by a party and thus receives insufficient analysis by the court, that issue is not “actually litigated” and cannot have preclusive effect in a later case. *See Chicago Truckers Drivers Pension Fund v. Century Motor Freight, Inc.*, 125 F.3d 526, 530 (7th Cir. 1997).

Courts have also held that an issue is not “actually litigated” if a party drops its defense relevant to it. *See Amadeo v. Principal Mut. Life Ins. Co.*, 290 F.3d 1152, 1159 (9th Cir. 2002) (“A voluntary dismissal of a claim prior to any adjudication and without any stipulated findings of fact does not actually litigate any issue”); *Adolph Coors Co. v. IRS*, 519 F.2d 1280, 1283 (10th Cir. 1975) (“To obtain the protection afforded by the doctrine of collateral estoppel an issue must

---

<sup>5</sup> The *Power* decision does not describe the affirmative defenses to the complaint at issue. However, that answer included a general invalidity defense. *See Power*, No. 08-309, D.E. 49, ¶ 30 (D. Del., filed Nov. 7, 2008), “Second Defense: Invalidity of the Asserted Patents” (“The ‘851 Patent, the ‘876 Patent, and the ‘270 Patent are invalid for failing to comply with the provisions of the Patent Laws, Title 35 U.S.C., including without limitation 35 U.S.C. §§ 102, 103, 112, 121 and/or under the doctrine of obviousness-type double patenting”). DRL’s affirmative defense of general invalidity is strikingly similar (*see pp. 4-5, supra*).

have been raised, litigated and actually adjudged on the merits in the first proceeding. Here, the overhead issue was raised but, because it was abandoned by the IRS, was not judicially determined”); *United States v. Young*, 804 F.2d 116, 118 (8th Cir. 1986) (“A fact established in prior litigation not by judicial resolution but by stipulation has not been ‘actually litigated’ and thus is the proper subject of proof in subsequent proceedings.”); *Serby v. First Alert, Inc.*, No. 09-4229, 2013 U.S. Dist. LEXIS 45942, at \*15 (E.D.N.Y. Mar. 27, 2013), citing *Restatement (Second) of Judgments* § 27, comment (e) (earlier settlement and Rule 41 dismissal with prejudice had no preclusive effect in later patent case concerning same patent because “[w]here a judgment between parties is entered by consent prior to trial on any issue, no issue may be said to have been fully, fairly or actually litigated”).

Based on the foregoing, Pozen’s motion cannot have preclusive effect since the issue of invalidity is not being “actually litigated.” Pozen’s motion is futile and should be dismissed.

#### **D. SUMMARY JUDGMENT IS NOT AN APPROPRIATE RELIEF**

Even if DRL somehow sought to pursue invalidity now, after failing to serve invalidity contentions, the appropriate relief would be for Pozen to seek a dismissal of DRL’s invalidity defense rather than moving for summary judgment. See *Aircraft Tech. Publishers v. Avantext, Inc.*, No. 07-4154, 2009 U.S. Dist. LEXIS 106526, at \*8-\*12 (N.D. Cal. Nov. 16, 2009) (granting dismissal of defendants’ invalidity counterclaims for “undermin[ing] the administration of justice by completely ignoring its obligations [to serve invalidity contentions] under the Patent Local Rules”).<sup>6</sup> Although it is unnecessary to dismiss DRL’s invalidity affirmative defense because it essentially became a nullity when DRL did not serve invalidity contentions, DRL nevertheless offered to withdraw the defense – an offer that was entirely appropriate. See *Malibu*

---

<sup>6</sup> Unlike the defendant in the *Aircraft* case, DRL did not interpose an invalidity counterclaim in this litigation; invalidity was only pled as an affirmative defense.

*Media*, 2013 U.S. Dist. LEXIS 55985, at \*33-\*35 (“acknowledg[ing] as withdrawn” certain affirmative defenses that defendants “voluntarily withdrew”; not ruling on those affirmative defenses in rendering its decision on plaintiff’s Motion to Strike or Summarily Dismiss Defendants’ Affirmative Defenses).

Pozen’s rejection of DRL’s offer to withdraw its affirmative defense of invalidity as insufficient for its purposes betrays Pozen’s true intent, which is either to find a way to get its amended validity contentions inserted into DRL I or to preclude DRL from pursuing its invalidity defense in DRL I. To the extent that any remedy were necessary in DRL II at this juncture, dismissal of DRL’s affirmative defense of invalidity in this case would be the more appropriate one in that DRL has not served invalidity contentions in DRL II.

#### IV. **CONCLUSION**

For the foregoing reasons, DRL respectfully requests that the Court deny Pozen’s motion for partial summary judgment that U.S. Patent No. 6,926,907 is not invalid.

Respectfully submitted,

Dated: August 5, 2013

s/ Alan H. Pollack  
Andrew J. Miller (amiller@buddlerner.com)  
Stuart D. Sender (ssender@buddlerner.com)  
Alan H. Pollack (apollack@buddlerner.com)  
Ellen T. Lowenthal (elowenthal@buddlerner.com)  
Michael W. Choi (mchoi@buddlerner.com)  
BUDD LARNER, P.C.  
150 John F. Kennedy Parkway  
Short Hills, New Jersey 07078  
Tel: (973) 379-4800

*Attorneys for Defendants  
Dr. Reddy’s Laboratories, Ltd. and  
Dr. Reddy’s Laboratories, Inc.*